REMARKS

Status of the Claims

Claims 2, 3, 6-9, 11-14, 19, 22-27, 30-38, 41, 42, 46-54, 59, 60, 63-67, 69-70 and 72-124 are pending in the present application. Claim 95 has been cancelled. Claims 122 and 123 have been added to claim subject matter cancelled from claim 19.

Rejection of Claims 2, 6, 7, 11, 12, 14, 19, 22, 23, 36, 37, 41, 42, 46-51, 53, 54, 66, 69, 70, 72-95, 112-115, 117, 118, 120 and 121 Under 35 U.S.C. 112, First Paragraph

Claims 2, 6, 7, 11, 12, 14, 19, 22, 23, 36, 37, 41, 42, 46-51, 53, 54, 66, 69, 70, 72-95, 112-115, 117, 118, 120 and 121 are rejected by the Examiner under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. This rejection is respectfully traversed. Reconsideration and withdrawal thereof are requested.

"Will cause an adverse reaction when injected into monkey eyes but will not cause an adverse reaction when applied to the skin of mammals"

Applicants do not agree that the specification does not support the above quoted phrase. Clearly, the intended reaction caused is an adverse one. See page 4, lines 7-18 of the specification, which recites "inflammatory response in the eye." Such a response is clearly an adverse reaction. Further, the

description on page 15, lines 4-15 expressly uses the phrase "adverse reactions." Also see Example 1, page 29, lines 6-11; Example 2, page 32, lines 9-15 and line 31; Example 6, page 43, lines 8-9; and Example 12, page 47, lines 13-16. Thus, the rejection is without basis. However, in order to expedite prosecution, the first recitation of the phrase "adverse reaction" has been cancelled and the phrase "inflammatory response" has been substituted therefor. This is clearly a non-narrowing claim amendment. The Examiner should refer to U.S. Patent 4,141,973 for a discussion of the relevant owl monkey eye test. This publication is incorporated by reference into the specification. See page 66, lines 23-25 of the specification. Further, note that U.S. Patent 4,303,676 discloses a similar test at col. 4, lines 45-55. Clearly, Applicants are referring to a well-known test in the art which is clearly described in the specification. Thus, the Examiner's rejection is clearly without basis and should be withdrawn.

""0.0001 mg to 100 mg"

The Examiner states that "the recitation in certain claims requiring 0.0001 mg to 100 mg… is considered new matter." Again, Applicants disagree. However, in order to expedite allowance, this phrase has been removed from claim 19. Applicants amendment

is clearly a non-narrowing claim amendment. Applicants have reintroduced this phrase into claim 122 in order to preserve this issue for appeal, if necessary.

It should be noted that the portion of the specification referred to by the Examiner on page 5 of the Office Action has been misinterpreted by the Examiner.

Accordingly, the rejection of claims 2, 6, 7, 11, 12, 14, 19, 22, 23, 36, 37, 41, 42, 46-51, 53, 54, 66, 69, 70, 72-95, 112-115, 117, 118, 120 and 121 under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement should be withdrawn by the Examiner.

Rejection of Claims 2, 6, 7, 11, 12, 14, 19, 22, 23, 36, 37, 41, 42, 46-51, 53, 54, 66, 69, 70, 72-95, 112-115, 117, 118, 120 and 121 Under 35 U.S.C. 121

Claims 2, 6, 7, 11, 12, 14, 19, 22, 23, 36, 37, 41, 42, 46-51, 53, 54, 66, 69, 70, 72-95, 112-115, 117, 118, 120 and 121 are rejected by the Examiner under 35 U.S.C. 112, first paragraph, as being indefinite. This rejection is respectfully traversed. Reconsideration and withdrawal thereof are requested.

"Adverse Reaction"

The Examiner's position is that the phrase "adverse reaction" is indefinite because this term is entirely subjective

from practitioner to practitioner. Applicants respectfully disagree for the reasons discussed above. However, in order to expedite prosecution, Applicants have cancelled the first recitation of the phrase objected to by the Examiner. The phrase "inflammatory response" is a term of art as recognized by Balasz. See U.S. Patent 4,141,973. Accordingly, the rejection with respect to "adverse reaction" as applied to the phrase "inflammatory response" should be withdrawn by the Examiner. As for the second recitation of the term "adverse reaction," this phrase is readily understood by one of ordinary skill in the art. Also note the Examples of the present application referred to above.

"Low Purity"

Claims 50, 51 and 95 are said to be indefinite because of the phrase "low purity." Although Applicants do not agree that this phrase is indefinite, this phrase has been deleted from the claims. This amendment is a non-narrowing claim amendment. Claim 95 has been cancelled without prejudice or disclaimer of the subject matter contained therein.

Claim 121 - "Pharmacologically Effective Amount" and "Nutritional Supplement"

The Examiner rejects the phrases "pharmacologically effective amount" and "nutritional supplement" because "it is unclear why the sole active ingredient in a nutritional supplement would be present in a pharmacologically effective amount." The Examiner should note that folic acid [nutritional supplement] prevents birth defects [pharmacological effect], and that vitamin C [nutritional supplement] prevents scurvy [pharmacological effect]. Both are nutritional supplements which when administered in a pharmacologically effective amount have the desired effect. In support of the Applicants' position, the Examiner's attention is directed to the attached publications. (e.g. (1) Kurtzweil, "How Folate Can Help Prevent Birth Defects", July 1996, and (2) Gordon, "Vitamin C Prevents Scurvy - Take in Moderation".) Also attached is a paper from the Markman Hearing in U.S. Patent 5,888,984 which recites similar terms as claimed herein, thereby supporting Applicants' definitions in the present application. Note that "pharmacology effective" means "an amount that is medically effective". Such a definition is hardly indefinite.

Accordingly, the rejections under 35 USC 112, second paragraph, should be withdrawn by the Examiner.

Claim Rejections - 35 U.S.C. §102

Claims 23, 42, 50, 51, 59, 66, 70, 72-76, 78, 80, 81, 91-95, 112, and 117-121 are rejected by the Examiner under 35 U.S.C. 102(b) as being anticipated by U.S. Patent 4,303,676 to Balazs for the reasons set forth on pages 7-9 of the Office Action.

This rejection is overcome due to the limitation "wherein said complex carbohydrate will cause an inflammatory response when injected into owl monkey eyes but will not cause an adverse reaction when applied to the skin of mammals or when delivered orally or mucosally to mammals." Contrary to the position taken by the Examiner, the phrase "adverse reaction" is a term of art and does not encompass "even a minuscule negative reaction to the composition." The Examiner must give Applicants' limitation appropriate and meaningful weight. The Examiner further alleges that the phrase "adverse reaction limitation encompasses the injection of any amount of the composition." Such an interpretation is simply not reasonable, since Applicants are using a phrase known in the art which does not have the meaning ascribed to it by the Examiner. Again, see the present Examples.

Further, Balasz clearly does not teach a pharmacologically effective composition, that is, one having an amount of active ingredient that is medically effective as claimed herein. The

Examiner has no legal basis for rendering Applicants' claimed term virtually meaningless.

As for the Examiner's position that if it exists it may be a food or drink, such an interpretation is not consistent with any description of Balasz. In this regard, Applicants' arguments of record are herein incorporated by reference.

Accordingly, reconsideration and withdrawal of this rejection are respectfully requested.

Claims 22, 23, 42, 50, 51, 59, 66, 70, 72-76, 78, 80, 81, 91-95, 112, and 117-121 are rejected by the Examiner under 35 U.S.C. 102(b) as being anticipated by WO 97/25051 to Turley for the reasons set forth on pages 9-11 of the Office Action.

The Examiner should note that the Turley reference expressly disclaims high molecular weights as claimed. See page 12, lines 8-15 of the Turley et al. reference.

This rejection is overcome due to the limitation "adverse reaction," which now reads as "inflammatory response." Contrary to the position taken by the Examiner, this phrase is a term of art and does not "encompasses the injection of any amount of the composition." Further, Turley does not disclose the claimed concentration(s).

On Page 11 of the Office Action, the Examiner attempts to rebut Applicants' arguments that Turley does not use HA of the claimed purity. The Examiner states that Turley discloses a

topical grade HA that "appears" identical to the claimed product. However, contrary to Turley, the claimed invention does not require sterilization. Finally Applicants' arguments of record regarding Turley are herein incorporated by reference. Thus, the claimed composition is not identical and reconsideration and withdrawal of the rejection are requested.

Claim Rejections - 35 U.S.C. §103

Claims 2, 6, 7, 11, 12, 14, 19, 22, 23, 36, 37, 41, 42, 46-51, 53, 54, 59, 66, 69, 70, 72-95, 112-115, 117 and 118-121 are rejected by the Examiner under 35 U.S.C. 103(a) as being obvious over U.S. Patent 4,303,676 to Balazs for the reasons set forth on pages 12-13 of the Office Action.

This rejection is traversed for the reasons stated above and for the reasons of record. The Examiner fails to give patentable weight to the phrase "wherein said complex carbohydrate will cause an inflammatory response when injected into owl monkey eyes but will not cause an adverse reaction when applied to the skin of mammals or when delivered orally or mucosally to mammals." The claimed amounts of the claimed active ingredient are clearly not suggested by Balasz. Indeed, the claimed active ingredient is not suggested by the Balasz reference. Thus, this rejection should be withdrawn.

Rejection of Claims Over WO 97/25051 to Turley et al. Under 35 U.S.C. 103; Rejection of Claims Over WO 97/25051 to Turley et al. in View of WO 92/22585 to Gallina Under 35 U.S.C. 103

Claims 2, 6, 7, 11, 12, 14, 19, 22, 23, 36, 37, 41, 42, 46-51, 53, 54, 59, 66, 69, 70, 72-95, 112-115, 117 and 118-121 are rejected by the Examiner under 35 U.S.C. 103 over WO 97/25051 to Turley et al. Claims 2, 6, 7, 11, 12, 14, 19, 22, 23, 36, 37, 41, 42, 46-51, 53, 54, 59, 66, 69, 70, 72-95, 112-115, 117 and 118-121 are rejected by the Examiner under 35 U.S.C. 103 over WO 97/25051 to Turley et al. in view of WO 92/22585 to Gallina. These rejections are respectfully traversed. Reconsideration and withdrawal thereof are requested.

Turley et al. clearly state that a molecular weight >1,000,000 daltons will not be orally effective (see page 12, lines 8-14). In fact, Turley et al. teach away from using any composition with a molecular weight >1,000,000 daltons. In the present invention, one of the molecular weight fractions recited by the amended claims is >1,000,000 daltons.

Finally, Turley et al. does not utilize HA of the claimed purity. The Examiner's reliance upon the Gallina reference does not correct this deficiency. Thus, the present invention is not obvious over Turley et al. optionally in view of Gallina.

Should there be any outstanding matters that need to be resolved in the present application, the Examiner is respectfully requested to contact Marc S. Weiner (Reg. No.

32,181) at the telephone number of (703) 205-8000, to conduct an interview in an effort to expedite prosecution in connection with the present application.

If necessary, the Commissioner is hereby authorized in this, concurrent, and future replies, to charge payment or credit any overpayment to Deposit Account No. 02-2448 for any additional fees required under 37 C.F.R. § 1.16 or under 37 C.F.R. § 1.17; particularly, extension of time fees.

Respectfully submitted,

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